DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Taiject Medical Device, Company Limited
C/O Dr. Jim-Son Chou
Vice President
Achevé Technology, Incorporated
P.O. Box 8853
Newport Beach, California 92658

Re: K042426
Trade/Device Name: TMD 0.5mL Safety Syringe (FA18 Series 0.5mL/FA58 Series U-100 Insulin/FA78 Series Tuberculin)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 3, 2004
Received: September 8, 2004

Dear Dr. Chou:

This letter corrects our substantially equivalent letter of September 22, 2004 regarding the trade name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SEP 2 2 2004

510(k) Summary of Safety and Effectiveness

for the TMD™ 0.5ml Safety Syringe

(FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin)

(per 21CFR807.92)

1. SPONSOR

Taiject Medical Device Co., Ltd.
1F, No. 22, KeDung 3 rd Road ,
Science-Based Industrial Park
Chu Nan, MiaoLi,
Taiwan 350
Republic of China
Tel: 886 37 585599
Fax: 886 37 585589
Contact person: Mr. David Huang
Date Prepared: September 3rd, 2004

2. DEVICE NAME

Proprietary Name:	TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin)
Common/Usual Name:	Safety Syringe
Classification Name:	Piston syringe (FMF) Anti-Stick Syringe (MEG)

3. Predicate Device (Legally Marketed Device):

Legally Marketed Device:

FA11 Series 1ml/FA51 Series U-100 Insulin/FA71 Series Tuberculin) with 510K number K031062 and
FA12 Series 3 ml/FA13 Series 5 ml with 510K number K022278

4. DEVICE DESCRIPTION

The TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin) is a single use, sterile, disposable syringes that is designed to reduce the risk of sharps injuries. The insulin syringe has scale lines in insulin

units. The Tuberculin syringe has scale lines of Tuberculin.

5. INTENDED USE

--- The TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml) is intended for injection of fluids into the body after the aspiration of fluid.

--- The TMD™ 0.5ml Insulin Safety Syringe (FA58 Series U-100 Insulin) is intended for use for subcutaneous injection of Insulin.

--- The TMD™ 0.5ml Tuberculin Safety Syringe (FA78 Series Tuberculin) is intended intra-dermal of Tuberculin.

All the three syringes above incorporate a safety feature that is designed to aid the reduction of needle stick injuries and the potential of syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same as the legally market device, FA11 Series 1ml/FA51 Series U-100 Insulin/FA71 Series Tuberculin) with 510K number K031062 and FA12 Series 3 ml/FA13 Series 5 ml with 510K number K022278

7. PERFORMANCE DATA

Performance data has been generated in compliance with the design control requirement and appropriate standards. The result demonstrated equivalent to the predicate devices.

8. COMPARISON INFORMATION

Comparison of the TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin) with Legally Marketed Device TMD™ Safety Syringe (FA12 Series 3ml/FA13 Series 5ml)

	Submission Device	**Legally Market Device**

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	TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin)	TMD™ Safety Syringe (FA11 Series 1ml/FA51 Series U100 insulin/FA71 Series Tuberculin)
Indications for Use	As a single use, hypodermic syringe. Safety feature protects after administration.	As a single use, hypodermic syringe. Safety feature protects after administration.
Volume (ml)	0.5ml	1ml
Needles Gauge	25~31Garge 5/8" or Shorter	25~31Garge 5/8" or Shorter
Needle Connection	Fixed needle	Fixed needle
Safety Features	Active safety feature, manually activated by users	Active safety feature, manually activated by users
Syringe Type	Plunger, Antistick with fixed needles	Plunger, Antistick with hypodermic needles
Material	Piston-Butyl Rubber Barrel, plunger, Needle holder – Polypropylene Lubricant	Piston-Butyl Rubber Barrel, plunger, Needle holder – Polypropylene Lubricant
Color	Parts- Clear Printing-Black Orange – Insulin Gray – Tuberculin Transparent – Safety syringe	Parts- Clear Printing-Black Orange – Insulin Gray – Tuberculin Transparent – Safety syringe

In summary, TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/FA58 Series U-100 Insulin / FA78 Series Tuberculin) is a smaller version of the legally marketed TMD™ Safety Syringe (FA11 Series 1ml/FA51 Series U-100 Insulin/FA71 Series Tuberclin) and FA12 Series 3 ml/FA13 Series 5 ml with 510K number K022278.

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Indications for Use

510(k) Number (if known): K042426

Device Name: TMD™ 0.5ml Safety Syringe (FA58 Series U-100 Insulin)

Indications For Use:

--- The TMD™ 0.5ml Insulin Safety Syringe (FA58 Series U-100 Insulin) is intended for use for subcutaneous injection of Insulin.

This syringe above incorporates a safety feature that is designed to aid the reduction of needle stick injuries and the potential of syringe reuse.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K042426

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Indications for Use

510(k) Number (if known): K042426

Device Name: TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml/ FA78 Series Tuberculin)

Indications For Use:

--- The TMD™ 0.5ml Safety Syringe (FA18 Series 0.5ml) is intended for injection of fluids into the body after the aspiration of fluid.

--- The TMD™ 0.5ml Tuberculin Safety Syringe (FA78 Series Tuberculin) is intended intra-dermal of Tuberculin.

All these two syringes above incorporate a safety feature that is designed to aid the reduction of needle stick injuries and the potential of syringe reuse.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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